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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,964	10/13/2005	Hiroshi Terada	050106	3134

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,964	TERADA ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/28/2005, 6/12/2006, 10/4/2006, 3/16/2007, 4/25/2007.

DETAILED ACTION

Claims 1-18 are pending and currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 is directed to a remedy, which falls under the statutory class of a composition of matter. Claim 1 fails to point out what is included or excluded in the remedy and is therefore directed to a composition with no components. Such a composition cannot be used to facilitate phagocytic activity of macrophages as recited in Claims 1 nor perform the further limitations recited in Claims 2-7 and 14, including the treatment and/or curing of the diseases listed in Claims 4-5. Claim 17 is directed to a remedy comprising lipopolysaccharide of Panoea agglomerans, and therefore does comprise components. Such a composition still cannot be used to cure AIDS, as is instantly claimed.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to a remedy. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites Gursel et al (Gursel et al, Models of Astrocytoma, Drug Discovery Today: Disease Models, 2005, 2, 77-83) and Contreras et al (Contreras et al, HIV Latency: Present Knowledge and Future Directions, 2006, 1(6), 733-745). Gursel et al teaches that there are no effective therapies for astrocytoma, the most common form of primary brain cancer, owing to its diffusely infiltrative nature (see abstract; Introduction). Contreras et al teaches that HIV hides in a latent form insensitive to current therapies and no known therapy can eradicate HIV from infected patients (see abstract).

2. The breadth of the claims

Instant Claims 1-7 and 14 encompass treating conditions, including cancer and AIDS, by using a composition with no components. Instant Claim 17 encompasses eradicating AIDS by using a remedy comprising

lipopolysaccharide of Pantoea agglomerans.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for the treatment or eradication of cancer nor HIV/AIDS by using a composition with no components. The specification provides no direction or guidance for the eradication of AIDS using a remedy comprising lipopolysaccharide of Pantoea agglomerans.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed remedy, which contains no components, could be predictably used to treat nor eradicate cancer nor AIDS as inferred by the claim and contemplated by the specification. In addition, no one skilled in the art would accept the assertion that the remedy according to Claim 17, which comprises a lipopolysaccharide, could be predictably used to eradicate AIDS, as is presently claimed. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. Claim 1 is directed to a remedy, which falls under the statutory class of a composition of matter. Claim 1 fails to point out what is included or excluded in the remedy and is therefore directed to a composition with no components. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Hara et al (O'Hara et al, Respirable PLGA Microspheres Containing Rifampicin for the Treatment of Tuberculosis: Manufacture and Characterization, Pharmaceutical Research, 2000, 17(8), 955-961; document provided by Applicant). O'Hara et al discloses treatment of tuberculosis by

administration of PLGA microspheres containing rifampicin (see title; abstract; introduction; results). The molecular weight of the PLGA is 82,500 (see materials). The microspheres further comprise polyvinylalcohol and have a median particle diameter of 2.76 to 3.45 microns (see ibid). Instant Claim 8 recites "for tuberculosis". The recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the PLGA microspheres containing rifampicin is fully capable of being used in tuberculosis therapy.

Claims 1-11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6248345 (hereafter '345). '345 discloses microspheres comprising PLGA wherein the polymer has a molecular weight of 18,000 daltons (see Example 9).

Instant Claim 15 recites "for tuberculosis". As stated above, if the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the microspheres comprising PLGA disclosed by '345 are fully capable of being used in tuberculosis therapy.

Instant Claim 16 recites a product by process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the

product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. In the instant case, there is no indication that the process disclosed in Instant Claim 16 results in a patentably distinct product.

Claims 1-7, 12 and 14 is rejected under 35 U.S.C. 102(b) as being anticipated by US 1739064 (hereafter '064). '064 discloses sucrose, a sugar, and its recovery from canned molasses (see page 1, lines 1-5). The only claim limitation in Claim 12 is that one of the disclosed components be present. Therefore Claim 12 encompasses any of the disclosed components in any place and form.

Claims 1-7, 14 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5346891 (hereafter '891). '891 discloses a lipopolysacchride produced by a strain of these species Pantoea agglomerans (see Claim 3). '891 does not disclose the cytotoxic effect on lung cancer cells. Although '891 does not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the product disclosed by '891. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent.

""[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP 2112, I.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

March 13, 2008